

K030387

MAR 11 2003

## 510(k) SUMMARY

Submitter's Name: C.T.M. Homecare Product, Inc.  
1663 Iowa Ave.  
Riverside, CA 92507  
909-788-8168

Date summary prepared: January 31, 2003

### Device name:

Proprietary name: C.T.M. Mobility Scooter HS-890  
Common or usual name: Electric scooter.  
Classification name: Motorized three-wheeled vehicle, Class II,  
21 CFR 890.3800.

### Legally marketed device for substantial equivalence comparison:

Laser 4 submitted by Pride Mobility Products Corp. and cleared for marketing under 510(k) #K003059.

### Description of the device:

The C.T.M. Mobility Scooter HS-890 is an indoor/outdoor electric scooter that is battery operated. It has a base with four wheels with adjustable padded seat, armrests, and headrests. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with a battery charger.

### Intended use of device:

The device is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

### Technological characteristics:

The device features and use parameters of the C.T.M. Mobility Scooter HS-890 and the Laser 4 are very similar. Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar, varying only slightly with selected parameters, such as the travel range and the grade the scooter can climb.

### Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted and the results included in the subject 510(k) submission.

### Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).



MAR 11 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

C.T.M. Homecare Product, Inc.  
c/o R.S. McQuate & Associates  
3636 E Columbine Drive  
Phoenix, Arizona 85032

Re: K030387  
Trade Name: C.T.M. Mobility Scooter HS-890  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: II  
Product Code: INI  
Dated: February 3, 2003  
Received: February 5, 2003

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

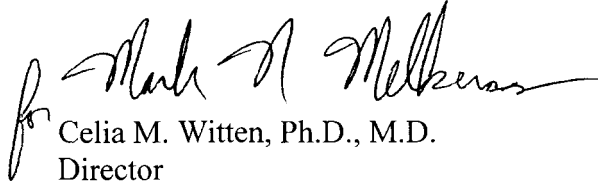
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Robert McQuate

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K030387

Device name: C.T.M. Mobility Scooter HS-890

Indications for Use:

The C.T.M. Mobility Scooter HS-890 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

(Please do not write below this line)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

*for Mark N. Milken*  
\_\_\_\_\_  
Division of General Restorative  
and Neurological Devices

510(k) Number K030387